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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,905	10/14/2003	James W. Voegelé	END0788USDIV1	3568
27777	7590	02/22/2010	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	
			NOTIFICATION DATE	DELIVERY MODE
			02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/684,905	Applicant(s) VOEGELE ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6, 15 and 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,712,773 to Viola in view of U.S. Patent No. 5,980,545 to Pacala et al.

In regard to claims 6, 15 and 17 – 20, Viola discloses a biopsy instrument including a base assembly (300) including a firing mechanism (Col. 10, lines 36 – 38); a probe assembly (10) detachably mounted to the base (Col. 10, lines 52 – 56), the probe assembly including a cutter assembly including a cutter (58) rotatable about its longitudinal axis; and a piercer assembly including a piercer (22) having a tissue piercing tip (30) and a side tissue receiving port (Col. 5, lines 11 – 12) spaced proximally from the tip, the piercer adapted to be carried distally toward a target by operation of the firing mechanism; and a transmission disposed proximally of the pierce, wherein the transmission is operable to provide motion to the cutter (Col. 6, lines 29 – 33), wherein the transmission receives rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission includes internal gear (70) that receives rotation from gear teeth (96') of drive gear (96) at an angle of 90 degrees with respect to the cutter's longitudinal axis. Furthermore, the Examiner considers the transmission to receive rotary motion about an axis angled with respect to the cutter's longitudinal axis in that the transmission receives rotation from the flexible shaft (226) that can be positioned at an angle with respect to the cutter's longitudinal axis (Figure 1). Viola

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discloses a medical device including a biopsy instrument and a source of motion (200; Col. 8, lines 12 – 35) separate from the biopsy instrument; the biopsy instrument comprising a housing (14); a piercer (22) extending distally from the housing and the piercer having a closed distal end (30) and a tissue receiving port (Col. 5, lines 11 – 12) spaced proximally of the closed distal end, the piercer supported with respect to the housing for firing the piercer into tissue (Col. 10, lines 36 – 41); a cutter (58) rotatable and translatable with respect to the tissue receiving port of the piercer (Col. 10, lines 46 – 48), the cutter having a longitudinal axis; and a transmission (70); wherein the biopsy instrument receives at least one input from the separate source of motion along an axis angled with respect to the longitudinal axis of the cutter in that the transmission includes internal gear (70) that receives rotation from gear teeth (96') of drive gear (96) at an angle of 90 degrees with respect to the cutter's longitudinal axis and transmit rotary motion to the cutter assembly gear mechanism (Col. 6, lines 28 – 33). The transmission converts the input to rotary motion of the cutter (Col. 6, lines 29 – 33). The transmission includes at least one gear (70). The instrument receives an input from the second source of motion through an elongate member (Col. 6, lines 33 – 39). The elongate member is a drive cable (Col. 6, line 35). The instrument receives a first input for translating the cutter from the separate source of motion (218) through a first elongate member (240), and wherein the biopsy instrument receives a second input for rotating the cutter from the separate source of motion (210) through a second elongate member (226). The separate source of motion is disposed in a control unit (200), and wherein the biopsy instrument receives input from the source of motion through a translation shaft (240) comprising a flexible cable in that all materials have at least some degree of flexibility, and from a rotation shaft comprising a flexible cable (226). Viola discloses a mechanism (300) operatively associated with the piercer for firing the piercer into tissue (Col. 9, lines 30 – 33; Col. 10, lines 36 – 38). Viola disclose a rotatable and translatable (Col. 10, lines 46 – 48) cutter (58)

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and a transmission, but fail to disclose the transmission including a bevel gear assembly supported by the base that receives rotary motion about an axis substantially perpendicular to the longitudinal axis of the piercer. Pacala et al. disclose a medical device including a rotatable and translatable cutter (Abstract) and a transmission, wherein the transmission includes a bevel gear assembly (28, 34) supported by a base that receives rotary motion about an axis substantially perpendicular to the longitudinal axis of the piercer (Figure 2). The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Viola and Pacala et al. teach transmissions for providing translation and rotation to a cutter it would have been obvious to one skilled in the art at the time of the invention to substitute one transmission for the other to achieve the predictable results of allowing the cutter (58) to rotate and translate in order to cut a tissue sample.

Response to Arguments

3. Applicant's arguments filed 1/4/10 have been fully considered but they are not persuasive. Applicant asserts that the combination of Viola with other references cited would not result in the claimed combination. However, the Examiner disagrees. Viola disclose a rotatable and translatable (Col. 10, lines 46 – 48) cutter (58) and a transmission, but fail to disclose the transmission including a bevel gear assembly supported by the base that receives rotary motion about an axis substantially perpendicular to the longitudinal axis of the piercer. However, Pacala et al. disclose a medical device having such a bevel gear assembly. The Examiner asserts that the combination of Viola in view of Pacala et al. teach the claimed invention.

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Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736